



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,110	01/25/2002	Carleton S. Hayek	1486-ARMY	1583

7590

02/18/2004

Francis A Cooch  
The Johns Hopkins University  
Applied Physics Laboratory  
11100 Johns Hopkins Road  
Laurel, MD 20723-6099

EXAMINER
----------

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/048,110

Applicant(s)

HAYEK ET AL.

Examiner

Carl H. Layno

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 and 23 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 11, 19, 20, 22 and 24 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 8-10 and 12-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Acknowledgment is made of applicant's preliminary amendment which was received by the Office on January 25, 2002. This document has been made of record in the file as Paper No.3.

#### ***Information Disclosure Statement***

2. Applicant's cited prior art, as disclosed by the search report for PCT/US01/06016 submitted in Paper No.1, has been cited made of record by the Examiner on the attached PTO-1449.

#### ***Drawings***

3. The drawings are objected to because the sheets of Figs.1-6 contain the labels "WO 01/62152" and "SUBSTITUTE SHEET (RULE 26)" printed on them. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

Art Unit: 3762

the invention. There appears to be a typographical error in the claim dependency of system claim 20, which, as submitted, depends from method claim 17 (there is no antecedent basis for the “system” of claim 17). To overcome this rejection, the Examiner recommends changing the claim to depend from claim 19.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 22, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott '733.

The Turcott '733 patent describes a method for monitoring a patient's heart (Fig.10) reading upon applicant's claimed method steps. The method of Turcott (Fig.10) records systolic sub-intervals, in this case those time periods associated with sound waves S1 and S4 (block 80), over a plurality of heart cycles (i.e. a 10 second interval of time -- block 82), computes associated energy values of these intervals 84, computes composite average energy values 86, and compares them to a calculated average energy value (block 92). All comparisons falling outside 1.5 x standard deviation of the average energy value is considered not normal and an alert counter is incremented (block 94).

In regard to claim 22, applicant's claim reads upon software/firmware running in the memory 18 connected to the microprocessor associated with the control electronics 12 of Turcott's device (Fig.1).

In regard to claim 24, applicant's attention is directed to Figs. 8 and 10, which show Turcott's software controlled ECG and heart sound management functions including ECG and sound collection (blocks 60 and 80), data management and analysis (blocks 68-78 and 84-94), and data storage (blocks 62, 66, 72, and 82).

8. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro et al '792 (PCT) (Applicant's prior art).

The Shapiro et al '792 PCT patent, cited by the Applicant, describes a system for diagnosing physical conditions of a patient (Fig.3) comprising a laptop computer having a processor 30 and a display 32 (p.5, lines 1-2) capable of performing applicant's data

Art Unit: 3762

management, storage and analysis, and an attached data collection unit comprising an ECG detector **14**, sound detector **12**, and A/D converter **28**.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bredesen et al '969 (Applicant's prior art).

The Bredesen et al '969 patent, cited by the Applicant as prior art, describes an intelligent stethoscope that monitors systolic murmurs during periods of cardiac systole (col.13, lines 14-15) and calculates the energy levels associated with these murmurs (col.13, lines 33-38) in order to distinguish the intensity of each murmur (i.e. faint, moderate, or intense). Frequencies and energy level amplitudes over threshold values (col.13, lines 44-45 and Fig.8E) are used to distinguish among normal heart sounds and a variety of abnormal murmurs, such as severe mitral stenosis (Fig.8G). See col.13, line 65 thru col.15, line 60.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2, 3, 6, 7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro et al '792 (PCT) in view of Bredesen et al '969 (both cited by the Applicant as prior art).

The Shapiro et al '792 (PCT) patent, cited *supra*, discloses a patient monitoring system (Fig.3) capable of monitoring both ECG signals and acoustic signals. Unlike applicant's claimed

Art Unit: 3762

method steps, the Shapiro et al device does not disclose details regarding the processing of sound detection signals using energy computations for detected systolic sub-intervals.

The Bredesen et al '969 patent, also described *supra*, recites a device whose operation reads upon applicant's claimed systolic interval monitoring and energy computing steps, but which does not teach the combination of acoustic heart sensing and the use of complementary ECG signal processing to perform applicant's claimed "parsing" function.

Lacking any criticality, to have substituted the stethoscope of Bredesen et al for the sound detector **12** (Fig.3) of Shapiro et al would have been an obvious substitution to one of ordinary skill in the art in view of the statement by Shapiro et al that the sound detector **12** is a "conventional microphone assisted stethoscope" (p.4, line 30).

In regard to claims 2 and 3, the modified Shapiro et al device would be capable of performing applicant's claimed "parsing" step since the detected ECG signals are used to delimit heart cycles (Abstract – lines 5-6).

In regard to claims 2, 6, and 7, applicant's attention is directed to Fig.3F of Bredesen et al '969 which shows a series of low and high pass filters which perform the function of applicant's claimed "bandpass" filters. The combined filters appear to define a band-pass frequency range of 50-800 Hz.

***Allowable Subject Matter***

12. Claims 21 and 23 are allowed.

13. Claims 4, 5, 8-10, and 12-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is an examiner's statement of reasons for allowance:

Independent claim 21 describes a method of optimizing a heart auscultation screening algorithm including the use of a "time-frequency transform" algorithm including "wavelets and bandpass filters" not found in the prior art.

Independent claim 23 recites the details of a "computer readable medium" whose contents perform the functional steps largely recited in method claim 2. Although the references of Shapiro et al '792 and Bredesen et al '969 were used against claim 2, the combined device in fact consisted of two separate devices, a stethoscope, and a laptop computer with attached ECG and respiration detectors, each would be inherently running its own separate programs from different "computer readable medium[s]" not from a single "computer readable medium" as claimed. The Examiner deems this difference noteworthy and patentably distinct.

15. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



Art Unit: 3762

*Conclusion*

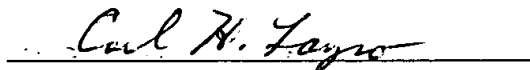
16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Little et al '164 and Cormier '308 patents are cited for their pertinent cardiac energy and sub-systolic signal processing, respectively.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. The current fax number for this Group is (703) 305-3590. Alternatively, for official correspondence, one may use the RightFax number (703) 872-9302 and for unofficial faxes (703) 746-4873. For after final actions, use (703) 872-9303.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO  
PRIMARY EXAMINER

CHL  
2/14/04